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APPLICATION NO. 09/133,127	FILING DATE 4/98	ZOU FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. UTSC584USC2
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EXAMINER KISHORE, G

ART UNIT 1615	PAPER NUMBER 25
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DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/122,427

Applicant(s)
Zou

Examiner
Gollamudi S. Kishore, Ph.D

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 26, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 52-56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 52-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

The request for the extension of time, filing under 1.114 and the preliminary amendment dated 9-26-01 are acknowledged.

Claims included in the prosecution are 1-9 and 52-56.

Claim Rejections - 35 U.S.C. § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 1, 52-53 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta (4,950,432).**

Mehta discloses preliposomal powders containing a drug and a mixture of phospholipids (note the abstract, columns 6-7, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argue regarding the process limitations in the composition claims. These arguments are not found to be persuasive since as pointed out before, applicant has not shown that the instant preliposomal powders are patentably distinct from the preliposomal powder of Mehta; applicant provides no experimental evidence to that effect.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. **Claims 1, 52-53 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta (5,811,119).**

Mehta discloses preliposomal powders containing retinoic acid and a mixture of phospholipids (note the abstract, columns 6-7 and Examples).

Applicant's arguments once again are on similar lines as for the rejection of claims over Mehta, 432 as above. These arguments have been addressed above.

Claim Rejections - 35 U.S.C. § 103

4. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 2-9 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (4,950,432) or (5,811,119) cited above, further in view of Unger (5,585,112), Isliker (5,089,602), Hsu (5,653,996) individually or in combination.**

Mehta does not disclose the use of surfactants such as tweens in the preliposomal preparations.

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Unger teaches that non-ionic detergents such as Tweens stabilize the liposome compositions (note col. 25, lines 38-48).

Isliker similarly teaches that Tweens could be used in liposome preparations; the liposome preparations are then lyophilized (Example 11).

Hsu teaches the use of Tweens in liposomal preparations (note col. 5, line 25 et seq.).

In essence, the secondary references all teach the routine practice in the art of the use of Tweens in liposomal preparations. Unger in particular teaches that these are liposomal stabilizers. The use of Tweens in the preparations of Mehta would have been obvious to one of ordinary skill in the art since these are stabilizers and routinely used in the art in liposomal preparations.

Applicant provides no specific arguments for this rejection: the rejection is maintained.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

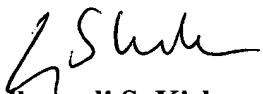
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

October 22, 2001